TO: Public and Private Vaccines for Children (VFC) Providers

FROM: Joyce Burgett, Manager
Montana Immunization Program

DATE: December 13, 2007

SUBJECT: Voluntary Recall of Certain Lots of PedvaxHIB® and COMVAX®

Merck & Co., Inc. has announced a voluntary recall of ten lots of PedvaxHIB® and two lots of Comvax®. These lots have been distributed to providers through the Vaccines for Children (VFC) Program as well as purchased directly from Merck or Merck distributors. We have identified that some of these lot numbers have been shipped to VFC providers in Montana. The lots that are being recalled are:

PRODUCT DESCRIPTION	LOT #	EXP. DATE
PedvaxHIB®	0677U	11 January 2010
PedvaxHIB®	0820U	12 January 2010
PedvaxHIB®	0995U	16 January 2010
PedvaxHIB®	1164U	18 January 2010
PedvaxHIB®	0259U	17 October 2009
PedvaxHIB®	0435U	18 October 2009
PedvaxHIB®	0436U	19 October 2009
PedvaxHIB®	0437U	19 October 2009
PedvaxHIB®	0819U	09 January 2010
PedvaxHIB®	1167U	10 January 2010
COMVAX®	0376U	05 January 2010
COMVAX®	0377U	08 January 2010

No potency concerns have been identified for these vaccine lots. Individuals who received vaccine from these lots should complete their immunization series with a Haemophilus b conjugate-containing vaccine not affected by this recall, but do not need to be revaccinated to replace a dose they received from a recalled lot.

All remaining doses in these effected lot numbers are to be returned to Stericycle, a company contracted by Merck to facilitate this process. Instructions on this process for returning the recalled doses are included in the Dear Doctor Letter (enclosed). An outline is provided below:

In order to ensure an effective recall and return process, it is important that you do the following for product **purchased directly from Merck**:

1. Please complete the enclosed Business Reply Card and the Packing Slip labeled "Non-VFC Vaccine" including entry of number of vials returned.

2. Mail the postage paid Business Reply Card even if you do not have any of the product identified above to ensure accountability.
3. Return all of the product identified above and the Packing Slip using the prepaid Shipping Labels to:

   Stericycle, Attn: Merck Returns
   2670 Executive Drive, Suite A
   Indianapolis, IN 46241

Credit for product will be issued at the price in effect for purchase directly from Merck at the time of purchase.

For any **Vaccines for Children (VFC) vaccine** from the affected lots, please do the following:

1. Contact Stericycle's Return Center at (877) 860-1200 or (317) 860-1200 for the necessary forms (if you do not have them).
2. Please complete the Business Reply Card and the Packing Slip labeled "VFC Vaccine" including entry of number of vials returned.
3. Mail the postage paid Business Reply Card even if you do not have any of the product identified above to ensure accountability.
4. Return all of the product identified above and the Packing Slip using the prepaid Shipping Labels to:

   Stericycle, Attn: Merck Returns
   2670 Executive Drive, Suite A
   Indianapolis, IN 46241

If you have both non-VFC and VFC vaccine to return, you may ship them together in the same shipping container as long as you have accounted for the vials separately using the appropriate forms outlined above.

We are asking all VFC Providers when returning any of the recalled doses to Merck that are VFC supplied to please complete the Montana DPHHS Wasted and Expired Vaccine Return form and fax the information to the Immunization Program at (406) 444-2920. We do not consider this vaccine to be wasted by any provider. This is the only way we will know how many VFC doses are being returned and how many VFC doses we need to try to replace in Montana.

Please be aware that this recall will affect the number of Hib doses available nationally. We expect to experience a Hib shortage. ACIP will be meeting to discuss whether or not the reduced number of doses will require a change in the Hib schedule. Any information regarding a change in the Hib schedule will be made available as soon it is released. In the meantime, the following steps can be taken to conserve Hib vaccine.

1. If you are using 4 doses of PedvaxHIB® (3 doses for the primary series and 1 dose for the booster), please discontinue this practice. When using PedvaxHIB® no more than 2 doses for the primary series should be used. Then 1 dose of either PedvaxHIB® or ActHIB® vaccine can be used for the booster dose.
2. Providers with shortages of vaccine may defer the booster (12-15 month-old) dose of Hib-containing vaccine in fully immunized children who are not otherwise at increased

risk of invasive Hib disease.

Information regarding this recall and any changes in the Hib schedule will be posted on our website at http://www.dphhs.mt.gov/PHSD/Immunization/immune-index.shtml.

If you have questions, please contact the Immunization Program at 444-5580. Thank you.

Enclosures: Montana DPHHS Wasted and Expired Vaccine Return form
Dear Doctor Letter
HIB Recall QA 12.12.07